Exhibit 02

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members *Plaintiffs,* v. XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES; AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, *Defendants.*	Civil Action No. 1:23-cv-00707

DECLARATION OF ADAM GLUCK
IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

I, Adam Gluck, declare as follows:

1. I am an employee of Sanofi, a global pharmaceutical company. I have worked at Sanofi US (Sanofi) for over six years, holding various roles within the company during my tenure. Presently, I serve as Senior Vice President and Head, U.S. and Specialty Care Corporate Affairs, where I lead Sanofi's corporate affairs efforts and align business strategy with reimbursement, government affairs, patient advocacy, communications and other key teams across a range of therapeutic areas including those addressing inflammatory diseases. As part of my responsibilities, I assess the impact that the Inflation Reduction Act of 2022 (IRA) will have on Sanofi's existing

and future pharmaceutical business. I also have expertise in the operation of the Medicare program, a program that has facilitated access to life-enhancing therapies and other treatment and services for many persons in the U.S. I regularly engage with Centers for Medicare & Medicaid Services (CMS) and other federal agency personnel on issues related to coverage and reimbursement of therapies under the Medicare program.

2. Sanofi is a leading global biopharmaceutical company operating in over 100 countries with its U.S. headquarters located in New Jersey. The company is dedicated to improving the lives of people everywhere through innovative biopharmaceuticals that prevent, treat, and cure illness and disease. To achieve this, we apply breakthrough science, unique technologies, dedicated research and development, manufacturing, and commercialization to transform the practice of medicine. Sanofi manufactures and markets various drugs that are covered by Medicare Part D and Medicare Part B. Sanofi operates at the forefront of science, at times on its own and in other instances through collaboration with other innovator companies through strategic partnerships and alliances to bring cutting-edge medicine to patients. Our pipeline of therapies is broad – it spans diverse therapeutic areas from oncology to immunology and inflammation, multiple sclerosis, neurology, rare disease, and rare blood disorders. Indeed, as of April 27, 2023, Sanofi's research and development pipeline includes 78 clinical-stage projects, 24 of which are in phase 3 or have been submitted to regulatory authorities for approval. These projects consist of examination of new molecular entities and existing therapeutics with potential additional indications or formulations. Through collaborative and individual efforts, Sanofi helps fuel the scientific innovation ecosystem that is so unique – and instrumental to patients' well-being – in the U.S.

3. Sanofi is an active member of Pharmaceutical Research and Manufacturers of America (PhRMA).

4. I understand that, on August 16, 2022, the IRA was signed into law. The IRA provides, in relevant part, for a Medicare price negotiation program, through which the U.S. Department of Health and Human Services (HHS) will establish a so-called "maximum fair price" (MFP) for particular single-source brand-name drugs or biologic products that HHS identifies as among the 50 Medicare Part D and 50 Medicare Part B drugs with the highest total Medicare expenditures. Starting in 2023, HHS will select 10 Medicare Part D products for negotiation, with corresponding MFPs going into effect in 2026. The number of products subject to mandated MFPs will increase each year, starting with 10 Part D products in 2026, and extending to an additional 15 Part D products in 2027, an additional 15 Part D or Part B products in 2028, and an additional 20 Part D or Part B products in 2029 and subsequent years. To be subject to the MFP, at least nine years (for small-molecule drugs) or 13 years (for biological products) must have elapsed from the product's Food and Drug Administration (FDA) approval or licensure date and there must be no generic or biosimilar on the market. While the MFP becomes effective for products based on these number of years since approval, products are selected for negotiation about two years prior to the applicability of the MFP, and HHS publishes the MFP more than one calendar year before its effective date.

5. Only limited groups of drugs are categorically exempt from IRA negotiation. For instance, the statute exempts from negotiation any orphan drug, which the IRA defines as "a drug… designated as a drug for only one rare disease or condition… and for which the only approved indication (or indications) is for such disease or condition." The statute specifies a product ceiling price (i.e., the MFP), but no price floor. Instead, HHS is directed to consider a

range of confidential, proprietary manufacturer information (including research and development costs, unit costs of production and distribution, and revenue and sales data), as well as evidence about "therapeutic alternatives", to inform the price offer. Once the MFP is established, pharmaceutical manufacturers must "provide access to [the MFP]" to eligible Medicare enrollees, as well as hospitals, physicians, and other providers in connection with Medicare utilization of the product. The U.S. government, in turn, will use the MFP as the basis for Medicare reimbursement of the relevant product. Part D sponsors generally must include on their formularies Part D products that are subject to an MFP.

6. While the IRA describes this program as a price "negotiation" to agree upon a maximum "fair" price, the program is far from mutually- or voluntarily-negotiated, or fair, in its design. The statute establishes a rigid "negotiation" process that, from the outset, is bounded by a capped MFP that varies within increasingly restrictive (i.e., lower) caps as more time has elapsed since FDA approval of the product. A manufacturer that does not comply with the negotiation provision as established by the IRA—by failing to timely enter into a "negotiated" agreement, agree to the maximum "fair" price, or submit required data to the Secretary—is subject to enormous penalties and so-called "excise taxes." These include (i) civil monetary penalties of up to 10 times the amount charged in excess of the MFP, for each unit of product, and (ii) an escalating "excise tax" calculated using a statutory "applicable percentage" starting at 65 percent of prior year sales, increasing to 95 percent after 270 days of noncompliance. The "excise tax" can equal up to 1,900 percent of the relevant product's price for each unit sold during the period of noncompliance. It continues to apply until (i) the manufacturer comes into compliance, (ii) there is the launch of a generic or biosimilar, and/or (iii) the manufacturer's termination of its Medicaid Drug Rebate Program, Medicare Part D Coverage Gap Discount Program, and Medicare Part D

Manufacturer Discount Program agreements with respect to all of the manufacturer's products across its entire portfolio. Confronted with the prospect of such enormous "excise taxes" for failure to comply with the government's ordained MFP, companies like Sanofi have no meaningful option other than to concede to application of the MFP.

7. Beyond this, the price negotiation program is being implemented absent ordinary processes that apply to agency action, with substantial, seemingly-unfettered, authority delegated to HHS to make critical program implementation decisions. Indeed, HHS has already started implementing the IRA in ways that pose significant harm to Sanofi, patients, caregivers, and others. For instance, on March 15, 2023, CMS issued a memorandum relating to the implementation of the first year of the IRA negotiation program. *See* "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 - 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" ("Initial Memorandum"). In issuing the Initial Memorandum, CMS made clear that, in the instances in which the agency was soliciting public comment, it was doing so "voluntar[il]y." Various guidance on the selection of drugs for mandatory price negotiation was issued as a "final [agency position], without a comment solicitation." In multiple instances in the Initial Memorandum, CMS demonstrated the extent to which it intends to exercise expansive authority to implement the price negotiation program in ways that will harm pharmaceutical innovation, patients, and the overall health system. For instance, the agency said it intends to define a "qualifying single source drug", for purposes of the negotiation program, by aggregating all products held by a manufacturer under separate Food and Drug Administration (FDA) approvals if the products contain the same active ingredient or active moiety – a position that runs contrary to the Medicare program's longstanding practice of granting a unique pricing and reimbursement profile to products with distinct NDAs or

BLAs. CMS also failed to provide clear, coherent criteria for determining when a generic or biosimilar is marketed for purposes of exempting the relevant brand product from IRA selection, opting instead to adopt a vague standard that the generic or biosimilar must be marketed in a "bona fide" manner. Further, the agency chose to interpret "total expenditures," for purposes of determining top-spend Part D products subject to negotiation, based on gross rather than net costs, without any meaningful explanation for this decision. And the agency said it will determine an "initial offer" (presumably an amount below the MFP) based on highly subjective, non-scientifically-rigorous criteria regarding cost-effectiveness and cost of alleged comparator products. The agency specified no floor for the "initial offer," nor did it outline a principled set of boundaries on (i) eligible therapeutic comparators or (ii) evidence that may inform the "initial offer." If manufacturers are aggrieved by, and disagree with, the initial offer they are given only cursory process to set forth their objection and a counter-offer. Even then, under a strict confidentiality policy, manufacturers are restricted from accessing material information about the initial offer or its basis, thereby limiting their ability to meaningfully review and voice their objections. And HHS's intended interpretation of the orphan drug exclusion, including the agency's independent addition of criteria in order to qualify for the exclusion, raises concerns. Specifically, CMS decided to require that all dosage forms and strengths and different formulations of the qualifying single source drug must satisfy various criteria in order for the orphan drug exclusion to apply to any dosage form or strength of a product. CMS foreclosed public comments on all such agency decisions around drug selection. Sanofi therefore has no opportunity to engage with the agency regarding these concerns and anticipated harms. In these ways and others, HHS has already demonstrated that it views itself as having unbounded freedom to implement the IRA as it chooses, absent judicial or other legal review, or public engagement or transparency.

8. On June 30, 2023, CMS released a second guidance memorandum with further instruction for the first year of the IRA negotiation program. *See* "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 - 1198 of the Social Security Act for Initial Price Applicability Year 2026" ("Revised Memorandum"). Rather than tempering its expansive use of authority in the wake of "many constructive, thoughtful, and helpful comments", the agency instead doubled down. CMS largely reiterated its prior guidance, including around the definition of a "qualifying single source drug", its use of a holistic bona-fide marketing standard to identify biosimilars, and its expansive interpretation of the orphan drug exclusion. The agency also failed to alleviate concerns regarding the lack of insight into the process CMS will use, or the information it will rely on, to determine the initial offer.

9. Based on my review of the IRA, Sanofi anticipates that it will be adversely impacted by the IRA negotiation program, raising constitutional concerns on multiple levels. Single-source brand drugs that have the potential to benefit patients across an array of indications, in particular, will be adversely impacted by the IRA. This is because incentives to run additional clinical trials on new indications will be drastically reduced if price cuts or fines are imposed before the full clinical potential of such drugs is realized. Sanofi has several such single-source brand name drugs that provide a clear example of the harmful impact of the agency's decisions on Sanofi. Based on current sales and guidance from CMS, Sanofi anticipates that at least one of these drugs may be among the products selected by HHS for MFP negotiation in the upcoming years. These drugs are first-in-class therapies without biosimilar alternatives. I believe that HHS is likely to select at least one of Sanofi's drugs for MFP negotiation in the next few years, with the MFP going into effect shortly thereafter.

10. For years, Sanofi has made considerable investments in development efforts related to multiple distinct indications for several drugs that significantly benefit patients. These drugs could generate many new regulatory submissions across indications and age groups. Sanofi has made significant investments in prospective new indications for patients with serious diseases that currently have inadequate or even no treatment options. These investments in clinical trials were undertaken at great risk given that many trials for other investigational treatments have failed to demonstrate significant clinical outcomes for vulnerable patient populations. Our willingness to take a calculated risks to improve patient care has led to the positive results from clinical trials in several instances. In some cases, these trial results represent significant achievements in an environment in which no new treatment approaches have been approved in more than a decade. However, this substantial investment in pursuing such indications is at risk of significant erosion in value if these later indications are ultimately approved by FDA and then, as CMS unilaterally determined will be the case for the first year of the program, is aggregated with longer-standing, already-approved, separate indications and therefore is selected for negotiation and subject to the MFP. If HHS selects one of Sanofi's drugs with a suite of indications (including newly approved indications) for mandatory MFP negotiation, as expected, the forced price reductions would significantly undermine the company's return on its development investments – returns that the company reasonably anticipated when it first decided to pursue these investments many years ago.

11. In some instances, Sanofi's price for its drugs was established based on a sustainable, fair and reasonable pricing approach that an independent, evidence-based organization, the Institute for Clinical and Economic Review (ICER), recognized as cost-effective. Often these products have also been subject to very limited price increases, consistent with Sanofi's publicly communicated pricing principles. Based on the statutory formula and cap on the

calculation of MFP, and what CMS has indicated about its process for formulating "initial offer[s]," Sanofi expects that the MFP imposed on its drugs, especially single-source drugs with multiple indications, will not be a fair or reasonable price, nor will it be consistent with the equitable, market-based pricing that Sanofi has long expected since the company first invested in these drugs. Sanofi makes sizeable investments in research and development across its portfolio. In 2022 alone, expenditures on research and development amounted to €6,706 million, reflecting 15.6% of Sanofi's net sales. The company's research and development expenses include investments in the development of various pipeline products and prospective new indications for existing products, some of which may never receive approval. The company has long undertaken these collective investments – either on its own or through thoughtful collaborations with other innovators – under the expectation that it will be able to obtain sufficient financial returns on products that receive approval and are commercialized. Sanofi has decades of experience as a pharmaceutical manufacturer and, therefore, ample experience with arms-length, free market-based price negotiations with customers and other counterparties. Sanofi has invested in the development of existing and prospective future therapies in reasonable expectation of returns under a continued, free market-based, level playing field with fair, independently-determined prices for its products.

12. Absent the IRA's coerced MFP negotiation, Sanofi would not (i) voluntarily enter into pricing negotiations with HHS for many if not most of its drugs, (ii) voluntarily agree to provide prices at the significant discounts mandated by the IRA, or (iii) voluntarily agree that the prices imposed by HHS are "fair." Instead, the IRA imposes on a manufacturer the sweeping obligation to provide access to a government-determined MFP across a range of supply chain transactions with customers and payors. Sanofi is further compelled to disclose to HHS

confidential, proprietary information, at threat of sizeable fines, as part of the "negotiation" process. The manufacturer and HHS do not "negotiate" the MFP on equal footing, and, instead, the MFP supersedes all free-market negotiations and serves as a compelled, government-established price cap. The MFP overrides the otherwise-applicable commercial market price for a product, instead authorizing the government to obtain the product for a mere fraction of its fair commercial market price. Such a price cap is unprecedented in our company's history of negotiating prices with health plans in connection with the Medicare program. This MFP price cap is not reflective of commercial market prices and is not a "fair" price to which Sanofi would voluntarily agree—in the absence of punitive consequences for non-compliance.

13. Sanofi will be compelled to participate in the IRA-prescribed negotiation process, and concede to the coerced MFP, for its drugs for at least the following two reasons. *First*, the statutorily-prescribed civil monetary penalties and "excise taxes" for failure to adhere to the negotiations and concede to the MFP are enormously punitive and will have serious adverse consequences for Sanofi, if they are imposed. Sanofi cannot pay an excise tax up to 1,900 percent of the relevant product's price for each unit sold for even a short duration of time without suffering significant, adverse financial harm and eroding the pipeline for research and development of future treatments to the detriment of patients. Instead, the penalties that the statute envisions leave Sanofi with no business choice other than to accept the coerced MFP price cap. *Second*, the statutory provision under which excise taxes cease to continue to apply (i.e., if a manufacturer discontinues its participation in the Medicaid Drug Rebate Program, the Medicare Part D Coverage Gap Discount Program, and the Medicare Part D Manufacturer Discount Program across the manufacturer's entire portfolio of products) provide illusory relief. Terminating these agreements means that Sanofi could no longer receive reimbursement for its entire portfolio of drug products

in the Medicaid, Medicare Part B, and Medicare Part D programs, which together account for roughly half of all prescription drug expenditures in the U.S. As a business matter, Sanofi derives billions of dollars every year from participation in these programs. Sanofi cannot afford to forego that revenue without significant detrimental consequences to its business. More fundamentally, Sanofi is committed to providing access to our medicines to the vulnerable populations that Medicare and Medicaid serve. Sanofi takes its commitment to patients seriously; in fact, it is the foremost consideration for everything the business does. If Sanofi no longer participated in these programs, millions of Medicaid and Medicare patients would be deprived of access to needed Sanofi therapies across multiple key therapeutic areas. This would be of enormous detriment to patients and the broader health care system, both of which would be deprived of scientific breakthroughs that stand to improve lives. Exiting the Medicare and Medicaid programs is thus anathema to Sanofi's mission and does not provide relief in mitigating the IRA's significant penalties for failing to concede to the negotiations and MFP.

14. As with all of its portfolio and pipeline future therapies, Sanofi has invested in the development of new indications with the reasonable expectation of returns under a continued, free market-based, level playing field with fair, independently-determined prices for its products. Yet, based on the statutory formula and cap on the calculation of MFP, Sanofi expects that the MFP for its drugs, and particularly for new indications, will not be fair or reasonable, nor will it be consistent with the equitable, market-based pricing that Sanofi has long expected since the company first invested in the development of many of these drugs.

15. The myriad harms of the IRA illuminate broader harms that Sanofi will confront across its entire portfolio of already-launched and prospective future therapies. In response to these harms, Sanofi will need to take concerted steps such as reevaluating the value of continuing

to pursue, and ultimately launching, new indications for approved drugs and other prospective therapies, given the challenge the company may confront in recouping substantial research and development investments. For certain therapies or indications, the company may need to address the prospect of launching at a financial loss. In order to avoid this consequence, Sanofi may reconsider – and perhaps ultimately abandon – clinical areas of pursuit, including prospective collaborations with other innovator companies, a detriment to the broader pharmaceutical innovation ecosystem. Sanofi would have no meaningful relief from these harms, given the magnitude of the "excise tax" that it would need to pay to avoid the MFP – a substantial amount that would bear no relationship to any alleged "harm" or "wrong" on the part of Sanofi.

16. Beyond these harms to Sanofi, there would be striking detriment to patients – patients who might benefit from newly-launched indications that address unique disease states, and patients who would benefit from other unpursued treatments for life-threatening conditions. For certain disease states in which Sanofi is a leading developer of pharmaceutical treatments – including but not limited to immunology and inflammation, diabetes, rare blood disorders, cardiovascular disease, oncology, multiple sclerosis and neurology – there could be substantial harm to Medicare patients, and the caregivers and families who support them. Patient quality of life, and livelihood itself in some instances, could be compromised – all due to a misguided drug price negotiation program being implemented without any reasonable or lawful constraints. Indeed, for some patients it could mean the difference between life and death.

17. Sanofi faces numerous additional harms from the price negotiation program, including in non-Medicare markets. For instance, because the list of drugs subject to negotiation will be published and publicly known (as will the MFP), Sanofi believes that the drug selection decisions and MFP publication will influence market dynamics and pricing outside the Medicare

program. This will compound the above-mentioned harms and further prevent Sanofi from pursuing the research and development of future therapeutics, on its own and through collaborations. Additionally, Sanofi expects that certain competitor Part D products will be selected for MFP negotiation, and therefore will generally be subject to guaranteed formulary coverage across all Part D plans. As Part D plan sponsors are only required to cover at least two products per therapeutic class (with the exception of defined "protected classes"), Sanofi reasonably anticipates it will be harmed when these competitor products are selected for MFP negotiation as Sanofi may either (i) lose formulary coverage for its competitive product, or (ii) be forced to offer artificially larger rebates/discounts to pharmacy benefit managers (PBMs). In either instance, Sanofi would be financially harmed, and patients could face meaningful disruption to their care without lower out-of-pocket costs. Relatedly, as PBMs may no longer receive rebates (or, if they do, may receive significantly reduced rebate amounts) in connection with MFP-negotiated products, Sanofi reasonably anticipates that PBMs will demand greater rebates/discounts and price concessions in negotiations for other products across Medicare and commercial market segments. And, for Part B-selected products, the price negotiation program may leave providers financially underwater. For Part B-selected products, reimbursement will be tied to the lower MFP price, regardless of whether the provider acquired the product at the traditional market-based price, potentially creating incentives for them to choose products on which they can recoup their costs, rather than products that are the most clinically efficacious for a given patient.

18. Beyond this, the process for implementing the IRA raises significant constitutional concerns and has already caused harm to Sanofi. The price negotiation program violates Sanofi's Fifth Amendment's Due Process right to be free from government deprivation of property without

constitutionally sufficient procedures. Sanofi has multiple property interests at stake, including its patent rights related to its drug products and its rights to recoup from its investments at market-based rates that are free from arbitrary and unlawful government constraints. The procedures that the government has set forth to respond to such deprivations are legally inadequate. HHS is implementing the price negotiation program absent notice-and-comment rulemaking and without even accepting comments on pivotal program elements such as the selection of drugs subject to negotiation. Sanofi therefore lacks processes through which to participate in, object to, and have transparency regarding the design and implementation of a program that dramatically implicates its property interests. The IRA statute further precludes judicial and administrative review of key agency decisions, leaving HHS with seemingly limitless authority to claim private property absent procedural protections. Sanofi has significant concerns about CMS's unilateral decisions – absent the benefit of any public comment or input. Sanofi has a strong interest in commenting on agency decisions and implementation. Yet, the process CMS has put forward for engagement around key decisions does not provide an adequate or meaningful opportunity for the company to engage with CMS. This is the case notwithstanding the fact that the agency's implementation decisions are critical to the business and its property interests and will have significant financial and other consequences for Sanofi and the patient populations Sanofi works to serve.

19. In sum, based on my review of the IRA, I am substantially certain that HHS will select one of Sanofi's drugs for price negotiation in the early years of the program. Based on the existing scheme and penalties and "excise taxes" contemplated by the IRA, Sanofi will be compelled to participate in the price negotiation program. The resulting "negotiated" prices will not be "fair" and will harm Sanofi. Various other components of the IRA will significantly, and adversely, impact Sanofi across the company's broader portfolio of products and across Sanofi's strategic collaborations with other innovators. Indeed, the very economic viability of certain products – including prospective new products or indications that Sanofi might launch on its own or through cooperative collaboration with others – will turn on whether the products are subject to negotiation. HHS will wield impermissible power to make decisions that could be financially crippling for the company. Sanofi is being deprived of constitutionally-afforded due process in safeguarding its most vital property interests – the fruits of years of research and development investments. Alongside these wrongs to Sanofi are significant harms to Medicare and other patients – innocent bystanders to HHS's impermissible action who stand to lose the best of science and innovation, including the potential miracle of cures.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 10th day of August, 2023.

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